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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,371	04/04/2005	Geoffrey Lilley Smith	ABL-007.1P US	5139

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,371	SMITH ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) 2-13,15-18,20-22,26,29,31,33,35,36,42,43 and 47-49 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 14, 19, 23-25, 27-28, 30, 32, 34, 37-39, 40-41, 44-46 and 50-53 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendments to the claims and new claims 51-53 filed January 5, 2005 have been acknowledged. Claims 2-13, 15-18, 20-22, 26, 29, 31, 33, 35-36, 42-43 and 47-49 are withdrawn from further consideration without traverse in the amendment filed on January 5, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 14, 19, 23-25, 27-28, 30, 32, 34, 37-39, 40-41, 44-46 and 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Sroller et al. (Archives of Virology, 1998, Vol. 143, p. 1311-1320).

The claimed invention is drawn to a method of vaccinating a subject comprising administering an immunogenic agent, wherein the immunogenic agent is a recombinant poxvirus, wherein the recombinant poxvirus genome does not comprise a functional gene encoding a 3β-hydroxysteroid dehydrogenase / Δ^5-Δ^4 isomerase (3β-HSD), wherein the recombinant poxvirus is an orthopoxvirus, parapoxvirus, avipoxvirus, suipoxvirus, mulluscipoxvirus or yatapoxvirus, wherein the recombinant poxvirus has no

coding sequence encoding a 3β-HSD or wherein the gene encoding the 3β-HSD is mutated such that the gene product has reduced activity; **or** wherein one or more mutation in the promoter cause expression of the gene to be compromised, leading to reduced levels of gene expression, wherein a recombinant poxvirus does not comprise a functional 3β-HSD and a pharmaceutically suitable carrier, wherein said composition further comprises one or more additives: a preservative, a stabilizer and an adjuvant, wherein the non-poxvirus gene or fragment that encodes an antigen is a non-poxvirus gene or fragment against the gene product of which a protective immune response in a subject is desirable, wherein the administration of said immunogenic agent is for prophylaxis of an infection caused by a pathogenic agent, wherein the non-poxvirus gene encodes an immunogenic peptide or polypeptide of an infectious pathogen, wherein the genome comprises a non-poxvirus gene or a fragment of a non-poxvirus gene which encodes an antigen, wherein said poxvirus is a vaccinia virus, a cowpox virus, a camelpox virus, or an ectromelia virus, hepatitis B virus preS2-S protein or *E. coli* guanine phosphoribosyl transferase, wherein the recombinant poxvirus is a vaccinia virus strain of Lister, Copenhagan, Wyeth, New York City Board of Health, NYVAC, Praha virus, DRYVAX Wyeth-derived virus, LIVP, IHD-J, IHD-W, Tian Tan, Tashkent, King Institute, Patwadanger, EM-63, Evans, Bern LC16m0 or MVA.

Sroller et al. teaches an immunogenic vaccine comprised of recombinant vaccinia virus, a poxvirus, with the A44L gene deletion, administered to mice. The A44L gene encodes the 3β-hydroxysteroid dehydrogenase / Δ^5-Δ^4 isomerase (3β-HSD) activity. The deletion of genes encoding such proteins can decrease the virulence and

enhance the safety and immunogenicity of live vaccines based on the recombinant vaccinia virus (p. 1311-1312, Introduction). Recombinant viruses expressing the preS2-S gene of hepatitis B virus (HBV) and gE of varicella-zoster virus (VZV) were tested where the foreign genes were inserted into the thymidine kinase gene of the vaccinia virus under the control of the 7.5k promoter (p. 1312, Material and Methods). The foreign antigens HBsAg and gE had a slightly higher antibody response than did the deletion mutants prepared by deleting the A44L gene in the highly attenuated P20 virus (p. 1318, first paragraph). Five vaccinia virus strains were tested: WR, Praha virus, DRYVAX Wyeth-derived (DD), LIVP and MVA (p. 1311, Summary). The vaccine administered to mice inherently comprises a pharmaceutically suitable carrier. The mice were inoculated against the pathogenic agents, HBV or VZV for treatment or prophylaxis (p. 1311, Summary). The fragment of the plasmid containing the E. coli guanine-xantine phosphororibosyl transferase gene was under the control of the vaccinia virus promoter (p. 1313, top of page).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sroller et al. (Archives of Virology, 1998, Vol. 143, p. 1311-1320) as applied to claims 1, 14, 19, 23-25, 27-28, 30, 32, 34, 37-39, 40-41, 44-46 and 51-53 above, and further in view of Dorner et al. (US Patent No: 6,265,183 B1, July 2001). The teachings of Sroller are described above. The claimed invention as described above wherein the recombinant poxvirus comprises a non-poxvirus gene or fragment, wherein the non-poxvirus gene or fragment is not a gene encoding varicella-zoster virus glycoprotein E.

Dorner et al. teaches a poxvirus vector (Abstract) with HIV-1 genes inserted in a vaccine composition (column 8, lines 24-34).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a recombinant poxvirus vector for another virus.

The person of ordinary skill in the art would have been motivated to make that modification because of the demand for viral vectors for immunogenic agents, and reasonably would have expected success because of the teachings of Sroller and Dorner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

May 23, 2006

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